ARC 3329C

PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)*"b."*

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to rescind Chapter 9, "Automated Medication Distribution Systems and Telepharmacy Services," and Chapter 21, "Electronic Data in Pharmacy Practice," and to adopt new Chapter 21, "Electronic Data and Automated Systems in Pharmacy Practice," Iowa Administrative Code.

These amendments were approved at the August 30, 2017, regular meeting of the Board of Pharmacy.

Pursuant to Iowa Code section 17A.7(2), this proposed rule making is the result of an overall review of administrative rules relating to automated medication distribution systems and electronic data in pharmacy practice. Chapter 9 is proposed to be rescinded to remove any overlap or inconsistencies of rules for telepharmacy practice found in 657—Chapter 13, "Telepharmacy Practice," recently adopted by the Board. Further, automated systems are increasingly commonplace in pharmacy practice, with safety and security measures well established, and the Board wishes to pare down the rules to identify the core minimum standards for pharmacies utilizing such systems. Minimum standards for automated systems are proposed to be added to Chapter 21. Several rules relating to notice and reports to the Board are not continued in the proposed rule making to lessen the burden on pharmacies using such automated systems.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on October 17, 2017. Such written materials may be sent to Terry Witkowski, Executive Officer, Iowa Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by e-mail at terry.witkowski@iowa.gov.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code sections 124.301, 124.306, 124.308, 147.107, 155A.27, 155A.33, and 155A.35.

The following amendments are proposed.

ITEM 1. Rescind and reserve **657—Chapter 9**.

ITEM 2. Rescind 657—Chapter 21 and adopt the following **new** chapter in lieu thereof:

CHAPTER 21
ELECTRONIC DATA AND AUTOMATED SYSTEMS IN PHARMACY PRACTICE

657—21.1(124,155A) Purpose and scope. The purpose of this chapter is to provide the minimum standards for the utilization of electronic data and automated systems in the practice of pharmacy and shall apply to all pharmacies located in Iowa.

657—21.2(124,155A) Definitions. For the purpose of this chapter, the following definitions shall apply:

"Automated data processing system" means an application that is used for prescription, patient, drug, and prescriber information; installed on a pharmacy's computer or server; and controlled by the pharmacy.

"Automated medication distribution system" or *"AMDS"* includes, but is not limited to, an automated device or series of devices operated by an electronic interface with one or more computers that is used to prepare, package, or dispense specified dosage units of drugs for administration or

dispensing. "AMDS" does not include electronic storage devices that do not have an electronic interface with one or more computers of the pharmacy.

"DEA" means the U.S. Department of Justice, Drug Enforcement Administration.

"Electronically prepared prescription" means a prescription that is generated utilizing an electronic prescription application.

"Electronic device" means an electronic, mechanical, or other device which is used to intercept communications and includes but is not limited to network, file and print servers; desktop workstations; laptop computers; tablets; mini-computers; smart phones; and similar devices.

"Electronic prescription" means an electronically prepared prescription that is authorized and transmitted from the prescriber to the pharmacy by means of electronic transmission.

"Electronic prescription application" means software that is used to create electronic prescriptions and that is intended to be installed on a prescriber's computers and servers where access and records are controlled by the prescriber.

"Electronic signature" means a confidential personalized digital key, code, number, or other method used for secure electronic data transmissions which identifies a particular person as the source of the message, authenticates the signatory of the message, and indicates the person's approval of the information contained in the transmission.

"Electronic transmission" means the transmission of an electronic prescription, formatted as an electronic data file, from a prescriber's electronic prescription application to a pharmacy's computer, where the data file is imported into the pharmacy prescription application.

"Facsimile transmission" or *"fax transmission"* means the transmission of a digital image of a prescription from the prescriber or the prescriber's agent to the pharmacy. "Facsimile transmission" includes but is not limited to transmission of a written prescription between the prescriber's fax machine and the pharmacy's fax machine; transmission of an electronically prepared prescription from the prescriber's electronic prescription application to the pharmacy's fax machine or printer; or transmission of an electronically prepared prescription from the prescriber's fax machine to the pharmacy's fax machine, computer, or printer.

"Intermediary" means any technology system that receives and transmits an electronic prescription between the prescriber and the pharmacy.

"Pharmacist verification" or *"verified by a pharmacist"* means the accuracy of a prescription drug is verified by a pharmacist, pharmacist-intern, or technician in an approved tech-check-tech program.

"Prescription drug order" or *"prescription"* means a lawful order of a practitioner for a drug or device for a specific patient that is communicated to a pharmacy, regardless of whether the communication is oral, electronic, via facsimile, or in printed form.

"Readily retrievable" means that hard copy or electronic records can be separated out from all other records within 48 hours of a request from the board or other authorized agent.

"Written prescription" means a prescription that is created on paper, a prescription that is electronically prepared and printed, or a prescription that is electronically prepared and transmitted from the prescriber's electronic device to a pharmacy via facsimile. A written prescription for a controlled substance shall be manually signed by the prescriber in compliance with federal and state laws, rules, and regulations.

657—21.3(124,155A) System security and safeguards. To maintain the integrity and confidentiality of patient records and prescription drug orders, any system, computer, or electronic device utilized shall have adequate security including system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records and prescription drug orders. Authentication credentials shall be securely maintained by the individual to whom the credentials are issued and shall not be shared with or disclosed to any other individual. Once a drug or device has been dispensed, any alterations in either the prescription drug order data or the patient record shall be documented and shall include the identification of all pharmacy personnel who were involved in making the alteration as well as the responsible pharmacist. An automated data processing system used for the receipt and processing of

electronic transmissions from a prescriber's electronic prescription application shall comply with DEA requirements relating to electronic prescriptions and shall be certified compliant with DEA regulations.

657—21.4 Reserved.

657—21.5(124,155A) Automated data processing systems. An automated data processing system may be used, subject to the requirements contained in this rule, for the storage and retrieval of prescription, patient, prescriber and drug data as well as data relating to the pharmacy staff utilization of the system.

21.5(1) *Electronic storage of hard-copy prescriptions.* A pharmacy that maintains an electronic copy of an original hard-copy prescription for a noncontrolled substance shall retain, in a readily retrievable format, the original hard-copy prescription as required in rule 657—6.8(155A) but shall be exempt from the requirement to record on the original hard-copy prescription the date and unique identification number of the prescription.

21.5(2) *Data retrievable and printable.* Any automated data processing system shall be capable of immediate retrieval (via computer monitor or hard-copy printout) of, at a minimum, any prescription, patient, prescriber, and drug data as well as data relating to pharmacy staff utilization of the system.

21.5(3) *Auxiliary procedure for system downtime.* A pharmacy utilizing an automated data processing system shall have a procedure that will maintain security and confidentiality of all data as well as ensure the legal dispensing of any prescription drug order in the event the system experiences downtime.

657—21.6(124,155A) Electronic prescription applications. A prescriber may initiate and authorize a prescription drug order utilizing an electronic prescription application that has been determined to maintain security and confidentiality of patient information and records and, if prescribing controlled substances via an electronic prescribing system, certified compliant with DEA regulations for electronic prescribing of controlled substances. The prescription drug order shall contain all information required by Iowa Code sections 155A.27 and 147.107(5). The receiving pharmacist shall be responsible for verifying the authenticity of an electronically prescribed prescription pursuant to rule 657—8.19(124,126,155A). A prescription that is electronically generated may be transmitted to a pharmacy via electronic or facsimile transmission or printed in hard-copy format for delivery to the pharmacy. A prescription that is transmitted by a prescriber's agent via electronic or facsimile transmission shall include the first and last names and title of the agent responsible for the transmission.

21.6(1) *Electronic transmission.* A prescription prepared pursuant to this rule may be transmitted to a pharmacy via electronic transmission. A pharmacy shall be certified compliant with DEA regulations relating to electronic prescriptions prior to electronically receiving prescriptions for controlled substances. The electronic record shall serve as the original record and shall be maintained for two years from the date of last activity on the prescription. Any annotations shall be made and retained on the electronic record.

a. An electronically prepared and transmitted prescription that is printed following transmission shall be clearly labeled as a copy, not valid for dispensing.

b. The authenticity of a prescription transmitted via electronic transmission between a DEA-certified electronic prescription application and a DEA-certified electronic automated data processing system shall be deemed verified by virtue of the security processes included in those applications.

c. A pharmacy shall ensure that no intermediary has the ability to change the content of the prescription drug order or compromise its confidentiality during the transmission process. The electronic format of the prescription drug order may be changed by the intermediary to facilitate the transmission between electronic applications as long as the content of the prescription drug order remains unchanged.

d. In addition to the information requirements for a prescription, an electronically transmitted prescription shall identify the transmitter's telephone number for verbal confirmation, the time and date

of transmission, and the pharmacy intended to receive the transmission as well as any other information required by federal or state laws, rules, or regulations.

e. If the transmission of an electronic prescription fails, the prescriber may print the prescription, manually sign the printed prescription, and deliver the prescription to the pharmacy via facsimile transmission in accordance with subrule 21.6(2).

21.6(2) *Printed (hard-copy) prescriptions.* An electronically generated prescription may be printed in hard-copy format for facsimile transmission or delivery to the pharmacy.

a. A prescription for a controlled substance shall include the prescriber's manual signature. Printed or hard-copy prescriptions for Schedule II controlled substances shall not be transmitted to a pharmacy via facsimile transmission, except as authorized in rule 657—21.7(124,155A).

b. If the prescriber authenticates a prescription for a noncontrolled prescription drug utilizing an electronic signature, the printed prescription shall be printed on security paper. Security features of the paper shall ensure that prescription information is not obscured or rendered illegible when transmitted via facsimile or when scanned into an electronic record system.

c. If the facsimile transmission of a printed prescription is a result of a failed electronic transmission, the facsimile shall indicate that it was originally transmitted to the named pharmacy, the date and time of the original electronic transmission, and the fact that the original transmission failed.

657—21.7(124,155A) Facsimile transmission of a prescription. A pharmacist may dispense noncontrolled and controlled drugs, including Schedule II controlled substances only as provided in this rule, pursuant to a prescription faxed to the pharmacy by the prescribing practitioner or the practitioner's agent. The means of transmission via facsimile shall ensure that prescription information is not obscured or rendered illegible due to security features of the paper utilized by the prescriber to prepare a written prescription. The faxed prescription shall serve as the original record, except as provided in subrule 21.7(1), shall be maintained for a minimum of two years from the date of the last activity on the prescription, and shall contain all information required by Iowa Code sections 155A.27 and 147.107(5), including the prescriber's signature. If the prescription is transmitted by an agent of the prescriber, the facsimile transmission shall include the first and last names and title of the agent responsible for the transmission. The pharmacist shall be responsible for verifying the authenticity of the prescription as to the source of the facsimile transmission.

21.7(1) *Schedule II controlled substances—emergency situations.* A pharmacist may, in an emergency situation as defined in 657—subrule 10.26(1), dispense a Schedule II controlled substance pursuant to a facsimile transmission to the pharmacy of a written, signed prescription from the prescriber or the prescriber's agent pursuant to the requirements of rule 657—10.26(124). The facsimile shall serve as the temporary written record required by 657—subrule 10.26(2).

21.7(2) *Schedule II controlled substances—compounded injectable.* A prescription for a Schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be transmitted by a prescriber or the prescriber's agent to a pharmacy via facsimile.

21.7(3) *Schedule II controlled substances—long-term care facility patients.* A prescription for any Schedule II controlled substance for a resident of a long-term care facility, as "long-term care facility" is defined in rule 657—23.1(155A), may be transmitted by the prescriber or the prescriber's agent to a pharmacy via facsimile. The prescription shall identify that the patient is a resident of a long-term care facility.

21.7(4) *Schedule II controlled substances—hospice patients.* A prescription for any Schedule II controlled substance for a patient in a hospice program licensed pursuant to Iowa Code chapter 135J or a program certified or paid for by Medicare under Title XVIII may be transmitted via facsimile by the prescriber or the prescriber's agent to the pharmacy. The prescription shall identify that the patient is a hospice patient.

657—21.8 and **21.9** Reserved.

657—21.10(124,155A) Automated medication distribution system (AMDS). Any pharmacy that utilizes an AMDS shall comply with these rules in addition to all applicable federal and state laws, rules, and regulations.

21.10(1) *Policies and procedures.* Pursuant to the requirements regarding policies and procedures in 657—subrule 8.3(5), each pharmacy utilizing an AMDS shall have policies and procedures that address all aspects of the operation of the AMDS to include, at a minimum:

a. Access to drugs and patient information,

b. Pharmacy personnel training in the proper operation of the AMDS,

c. Methods to ensure accurate stocking of the AMDS pursuant to subrule 21.10(2),

d. Confidentiality of patient information,

e. Routine and preventative maintenance of the AMDS according to manufacturer recommendations,

f. Packaging and labeling of prescription drugs loaded into or dispensed from the AMDS that is in compliance with federal and state laws, rules, and regulations, and

g. Security and control of the prescription drugs maintained and utilized in the AMDS to include:

(1) Drug loading, storage, and records.

(2) Drugs removed from system components but not used.

(3) Inventory.

(4) Cross contamination.

(5) Lot number control.

(6) Wasted or discarded drugs.

(7) Controlled substances.

21.10(2) *Stocking the AMDS.* The pharmacy shall have adequate procedures in place to ensure the accurate stocking of drugs into an AMDS using barcode scanning technology. Only a pharmacy technician, pharmacist-intern, or pharmacist shall be allowed to participate in the stocking of the AMDS.

21.10(3) *Pharmacist verification of drugs dispensed from AMDS.*

a. When an AMDS only dispenses drugs that were prepackaged and verified by a pharmacist prior to being stocked in the AMDS and there was no further manipulation of the drug or package other than affixing a patient-specific label, such drugs shall not require additional pharmacist verification prior to administration or dispensing to the patient or authorized representative.

b. When a drug is stocked in an AMDS and undergoes further manipulation, such as counting and packaging, such drugs shall require pharmacist verification prior to dispensing to the patient. Such verification shall be documented.

21.10(4) *Placement of AMDS.*

a. An AMDS placed outside a pharmacist's direct supervision shall only dispense pharmacist-verified packages in compliance with paragraph 21.10(3)*"a."*

b. An AMDS that manipulates, including but not limited to counting, packaging, or labeling, prescription drugs for subsequent patient dispensing shall only be utilized in a pharmacy under the direct supervision of a pharmacist, except in an approved telepharmacy pursuant to 657—Chapter 13.

657—21.11(124,155A) Pharmacist verification of controlled substance fills—daily printout or logbook. The individual pharmacist who makes use of the pharmacy prescription application shall provide documentation of the fact that the fill information entered into the pharmacy prescription application each time the pharmacist fills a prescription order for a controlled substance is correct. If the pharmacy prescription application provides a hard-copy printout of each day's controlled substance prescription order fill data, that printout shall be verified, dated, and signed by each individual pharmacist who filled a controlled substance prescription order. Each individual pharmacist must verify that the data indicated is correct and sign this document in the same manner as the pharmacist would sign a check or legal document (e.g., J. H. Smith or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order fill data shall be generated by and available at each pharmacy using a computerized pharmacy prescription application within 48 hours of the date on

which the prescription was dispensed. The printout shall be verified and signed by each pharmacist involved with such dispensing. In lieu of preparing and maintaining printouts as provided above, the pharmacy may maintain a bound logbook or separate file. The logbook or file shall include a statement signed each day by each individual pharmacist involved in each day's dispensing that attests to the fact that the prescription information entered into the pharmacy prescription application that day has been reviewed by the pharmacist and is correct as shown. Pharmacist statements shall be signed in the manner previously described. The logbook or file shall be maintained at the pharmacy for a period of two years after the date of dispensing.

These rules are intended to implement Iowa Code sections 124.301, 124.306, 124.308, 147.107, 155A.27, 155A.33, and 155A.35.